Certificate Program Objectives:

Upon completing the Clinical Research Operations Certificate program, participants will be able to:

1. Explain the marketing approval process (pre-clinical to phase IV) for new drugs, biologics, and devices from operational, scientific, and regulatory perspectives.
2. Compare and contrast differences in the drug approval process in the U.S. to other countries and regions.
3. Distinguish each phase of product development in terms of overall objections, applicable study designs, populations studied, types of clinical endpoints, and connection to information included in the approved product labeling.
4. Select appropriate regulations and guidelines, used in the U.S. and abroad, to guide specific activities related to new biopharmaceutical and device product development from the site, sponsor, and subject perspectives.
5. Examine and critique approaches for ensuring high quality clinical trial data related to protocol and case report form design, site activities, monitoring, data management, statistical analyses, safety reporting, and development of regulatory reports.
6. Construct a model for forecasting and managing the resources necessary for the execution of clinical trial programs including budget, timelines, and deliverables.